IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Valentine B. Andela (Cancer-Africa™)	)	
	)	
Plaintiff	)	
	)	**CASE #09-2487**
vs	)	
	)	**CIVIL COMPLAINT**
American Association for Cancer Research et al	)	**JURY TRIAL DEMANDED**
	)	
Defendant	)	
	)	

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SECOND AMENDED COMPLAINT

1. Plaintiff institutes this action for actual damages, statutory damages, punitive damages, injunctive relief, attorney fees, and the cost of pursuing this action against the defendant for gross dereliction of duty; coercion, fraud and conspiracy to defraud; intentional infliction of emotional distress; violation of the Lanham Act §43 (a), 15 U.S.C. § 1125(a) and; violation of the Sherman Antitrust Act, 15 U.S.C. §§ 1, 2.

THE PARTIES

I-The Plaintiff.

2. Valentine B. Andela (hereon "Dr Andela") is a U.S. based physician-scientist of African (Cameroonian) extraction and with internationally recognized credentials in translational cancer research and international technology transfer. Dr Andela's interest in international cancer research and technology transfer to Africa is backed by a professional master of arts in international administration and a certificate in global health diplomacy (i.e. "the multi-level, multi-actor negotiation processes that shape and manage the global policy environment for health issues which transcend national boundaries and governments and call for actions on the global forces and flows the determine the health of people" (Ilona Kickbusch, 2006, 2007)).

3. Through hard work and dedication, Dr Andela became a productive physician-scientist as evidenced by several first author peer reviewed research publications to his credit; the impact factor of his research publications, one of which is the most accessed research article of all time in the journal Molecular Cancer (http://www.molecular-cancer.com/mostviewedalltime); several merit based awards for excellence in cancer research such as a James P. Wilmot Fellowship Award (2001-2004) and an American Association for Cancer Research – American Family Life Assurance Company (AACR-AFLAC) Scholar-in-Training Award "for promising an meritorious cancer research", granted during the inaugural American Association for Cancer Research – National Cancer Institute – European Organization for Research and Training in Cancer (AACR-NIC-EORTC) international conference: "Molecular Targets and Cancer Therapeutics: Discovery, Biology and Clinical Applications", October of 2001, Miami Beach, Florida.

4. In March of 2003, Dr Andela was awarded an International Cancer Research and Technology Transfer (ICRETT) award, administered by the International Union for the Fight Against Cancer (UICC – Geneva, Switzerland) with federal funds from the U.S. National Cancer Institute – National Institute of Health (NCI - NIH) under contract # NO2-CO_91012. This enabled Dr. Andela to found, incorporate and develop Cancer-Africa™, initially as a "web-based interactive platform designed to enhance south-south dynamics and north-south cross-collaboration in cancer education, research and practice" and then as "an action-oriented think-tank that engages and promotes strategically-driven partnerships that are multi-constituent focused, technically sound and ethically and socially responsible".

5. Dr Andela is listed in the Marquis Who's Who in America® since 2004 -"inclusion in which is limited to those individuals who have made outstanding contributions to their respective fields of endeavor and who have thereby contributed to the

betterment of contemporary society". In 2005, Dr Andela was granted permanent resident status in the United States through the exclusive "U.S. national interest waiver" category for outstanding professionals.

6. Dr Andela's commitment to translational cancer research and international technology transfer to Africa is strategically oriented toward the effective integration of Africa in the global cancer effort; accessing and unleashing the market potential for cancer research and services in Africa; broadening the knowledgebase of cancer; speeding up innovation and discovery; enhancing competitiveness and improving consumer welfare.

7. An important precedent informs and legitimizes the strategic orientation of Dr Andela (Cancer-Africa™): much of the proof of principle and fundamental algorithms in clinical cancer chemotherapy were gleaned from international clinical trials on the African Burkitt's lymphoma that were conducted in Africa in the 1960's i.e. in the wake of independence movements and participatory democracies in Africa and with the active participation and contribution of the locals. These successes were celebrated in the 1972 Albert Lasker Award (the American equivalent of the Nobel Prize in Medicine) for medical research on the chemical treatment of cancer and were critical to the enactment of the National Cancer Act and its promulgation as "The War Against Cancer" by President Richard Nixon in 1971. Despite Africa's critical contribution to the commons, it quickly fell under an anticommons regime.

8. As Rebecca S. Eisenberg points out in her article entitled 'Public Research and Private Development: Patents and Technology Transfer in Government Sponsored Research', *Virginia Law Review* 82, 1663 (1996); by the 1980's biomedical research moved from a commons (public, non-rival and non-excludable) model toward an anticommons (privatization, rival and excludable) model. In an effort to promote commercial development of new technologies, the U.S. Congress

passed the Bayh-Dole Act which encouraged universities and other institutions to patent discoveries arising from federally supported research and development and to engage in technology transfer to the private sector including but not limited to spinning off biotechnology firms. An intrinsic risk of the anticommons (privatization, rival and excludable) model is the emergence of a "tragedy of the anticommons" – such as articulated by Michael A. Heller in 'The Tragedy of the Anticommons: Property in the Transition from Marx to Markets', *Harvard Law Review* 111, 621 (1998) – whereby resources are used inefficiently or are simply underused because too may people have rival claims and seek excludable (veto) rights to the transformation of a common resource and to value creation.

9. Cancer remains a leading cause of morbidity and mortality and is associated with incalculable pain, suffering and catastrophic health spending. Every projection indicates a rising cancer burden coupled to spiraling cost increases in cancer research and services. The Pharmaceutical Research Manufacturers of America (PhRMA) estimated that of the 400 cancer medicines that were being tested in clinical trials in 2005, a significant fraction did not prove useful and the many that did faced delays in getting approved because clinical participants were low (<3% of U.S. patients participate in clinical trials) because of cost constraints (70-90% of the cost of conducting clinical trials in the U.S. are administrative costs). Thus the cost of research and development increases and this cost increase is passed on to the consumer who is in turn constrained by the cost of access to life saving therapies. The end result is a vicious cycle of spiraling costs.

10. The critical contribution of Africa, while recognized in the 1972 Albert Lasker Award, is prominently absent from subsequent narratives on the subject matter e.g. a recent review article entitled "A History of Cancer Chemotherapy" which was published as part of the American Association for Cancer Research (AACR) Centennial Series in its flagship journal *Cancer Research*, on the 1st of November,

2008; Issue # 68: Volume 21, pages 8643-8653. This systematic exclusion of Africa from critical narratives plays into "the tragedy of the anticommons" and contributes to market distortions, increased barriers to entry, restrictions on competition and research output, increases in rent (prices) and ultimately a reduction in consumer purchasing power and access to life saving therapies.

11. More than before, much more would be gained from a cogent international research effort in Africa given that its variegated population genetics is essential to laying bare the complexities and contrasts in cancer biology and accelerating the development of the new generation of "molecular targeted" cancer therapies. Furthermore, there is a tremendous wealth of cancer patients available for enrollment in clinical trials at a fraction of cost in Africa. As stated by the U.S. National Cancer Institute, in its *Cancer Clinical Trials: Basic Workbook*, "we will never know the true effectiveness of a cancer treatment or a way to prevent cancer unless more people are involved in clinical trials" and 3% of U.S. adults with cancer participating in clinical trials is "far fewer than the number needed to answer the most pressing cancer questions quickly". Accessing and effectively engaging the repository in Africa begins with "a fundamental extension in morality", to paraphrase the subtitle of the landmark essay on "The Tragedy of the Commons" published by Garrett Hardin in the most highly regarded scientific journal of the American Association for the Advancement of Science, *Science*, in 1968 and which is central to all debates in economics, law and science that revolve around the privatization of the commons. According to Michael A. Heller and Rebecca S. Eisenberg – coauthors of a critical article entitled "Cancer Patents Deter Innovation? The Anticommons in Biomedical Research" published on the 1st of May 1998, in *Science* Vol. 280, pages 698-701 - "three structural concerns caution against uncritical reliance on markets and norms to avoid a biomedical anticommons tragedy: **i**) the transaction costs of rearranging entitlements; **ii**)

heterogeneous interests of owners and; **iii**) cognitive biases of researchers". Heller and Eisenberg admonish that "once an anticommons emerges, collecting rights into usable private property is often brutal and slow"

12. It is against the backdrop of an "anticommons" that Cancer-Africa™ is positioned as "an action-oriented think-tank that engages and promotes strategically-driven partnerships that are multi-constituent focused, technically sound and ethically and socially responsible". The success of Cancer-Africa™ is predicated on a finding the right mix of social and business entrepreneurship to overcome the structural impediments of an "anticommons" and growing as a company that provides cancer relevant technology, information solutions, integrated project management systems and contract research services in Africa.

13. That the inception of Cancer-Africa™ was supported by a U.S. National Institute for Health (NIH) "international cancer research and technology transfer" award is testament to the fact that its strategic orientation is consistent with the NIH "roadmap" for medical research in the 21st century and not something out of left field.

14. The NIH "roadmap" contains three primary themes bridging medical research across each institution within the NIH, including the National Cancer Institute. These three themes include:

- New pathways to discovery – to advance our understanding of biological systems and to build a better toolbox for medical research;
- Research teams of the future - to stimulate new ways of combining skills and disciplines in the physician, biological, and social sciences to realize the great promise of medical research; and
- Re-engineering the clinical research enterprise - to contribute to accelerating and strengthening clinical research by adopting a systematic infrastructure that will better serve the evolving field of scientific discovery.

15. At all times and in all things material and relevant to this complaint, Dr Andela has been the managing officer of Cancer-Africa™

II-The Defendant.

16. Defendant, the American Association for Cancer Research (AACR) is "the world's oldest and largest professional organization dedicated to advancing cancer research". "The mission of the AACR is to prevent and cure cancer through research, education, communication, and collaboration. Through its programs and services, the AACR fosters research in cancer and related biomedical science; accelerates the dissemination of new research findings among scientists and others dedicated to the conquest of cancer; promotes science education and training; and advances the understanding of cancer etiology, prevention, diagnosis, and treatment throughout the world. The AACR "is the authoritative source of information about advances in the causes, diagnosis, treatment and prevention of cancer. By accelerating the growth and spread of new knowledge about cancer, the AACR is on the front lines of the quest for prevention and cure." The main office of the AACR is located at **615 CHESTNUT STREET, 17th FLOOR, PHILADELPHIA, PENNSYLVANIA, 19106-4404**. The AACR has more than 27,000 members in about 90 countries. "The AACR marshals the full spectrum of expertise from the cancer community to accelerate progress in the prevention, diagnosis and treatment of cancer through high-quality scientific and educational programs." "The AACR Foundation for the Prevention and Cure of Cancer is a 501(c)(3) public charity that provides financial support for scientific research, education and communication. The Foundation funds programs deemed by the AACR to be of the highest priority and impact."

17. The AACR is the scientific partner for the Stand Up To Cancer (SU2C) initiative, which is described as "an unprecedented collaboration uniting the major television networks, entertainment industry executives and celebrities, and prominent leaders in cancer research and patient advocacy in a major new

initiative to move groundbreaking cancer research out of the lab and into the clinic".

18. Stand Up To Cancer (SU2C) projects have included:

A) A nationally televised fundraising event that aired simultaneously in the United States on ABC, CBS and NBC at 8 p.m. EST and PST on September 5, 2008, and internationally in more than 75 countries ;

B) Standup2cancer.org - an online community for everyone affected by cancer;

C) A public awareness campaign featuring celebrities and members of the public to mobilize support for the campaign.

According to SU2C

- 70 percent of SU2C donations will directly fund the best and brightest investigators from leading institutions across the country and internationally to work in collaborative, multi-disciplinary "Dream Teams." These Teams will pursue the most promising research, accelerating the discovery of new therapies for cancer patients and/or advancing efforts in cancer prevention research -- with sufficient resources to conduct intense, goal-directed, team-oriented approaches to a cancer problem, these Teams can be successful. The more funds raised, the more Dream Teams that can be funded.
- 20 percent of SU2C donations will directly fund innovative, high-risk, high-reward innovative cancer research proposals that often are not supported by convention funding sources, but have the potential to improve the lives of cancer patients. The hope is that ideas for new Dream Teams will emerge from these novel projects.
- 10 percent of SU2C donations will be invested to the Stand Up To Cancer reserve to continue its mission of funding cutting-edge research and bringing effective new treatments to cancer patients in the shortest time possible.

19. In 2008, SU2C raised more than $100 million for cancer research- "all of which will fund cutting-edge research and bring effective new treatments to cancer patients in the shortest time possible. The first round of three-year grants — that total $73.6 million — were given to five multi-disciplinary, multi-institutional research Dream Teams and SU2C's next round of funding — Innovative Research Grants for individual investigators — will be announced later this year"

20. As a partner in the SU2C initiative, the "AACR provides scientific oversight and [ ] conduct[s] expert peer review and grants administration for Stand Up To Cancer.

AACR is highly regarded for its scientific excellence, scientific brain trust in all subfields of cancer research, and for its peer review process that is fast, flexible, rigorous and transparent. The scientific leadership provided by AACR is critical to achieving SU2C's mission to translate the most promising cancer research into real advances in cancer treatment and prevention as quickly as possible".

21. The AACR's flagship journal *Cancer Research* "is the most frequently cited cancer journal in the world. The journal publishes significant, original studies, reviews, and perspectives on all areas of basic, clinical, translational, epidemiological, and prevention research in cancer and the cancer-related biomedical sciences. […] Papers are stringently reviewed, and only those that report results of novel, timely, and significant research and meet high standards of scientific merit are accepted for publication." "Cancer Research is cited more than 100,000 times a year".

22. It is alleged that the Editor-in-Chief, the Senior Associate Editor, an Associate Editor, a Reviewer and the Assistant Director, Editorial Systems & Journal Manager of *Cancer Research* engaged in a conspiracy, common enterprise and common course of conduct, the purpose of which is and was to engage in the violations of law alleged in this complaint. This conspiracy, common enterprise and common course of conduct, continues to be present.

23. The AACR has vicarious liability under the common law doctrine of agency *respondeat superior* i.e. the responsibility of the superior for the acts of their subordinate, or, in a broader sense, the responsibility of any third party that had the "right, ability or duty to control" the activities of the violators.

24. Under the instrumentality officers, editors and directors have a general fiduciary duty of loyalty and care which must govern all their corporate conduct and whenever there is evidence of breach duty by gross negligence or acts in bad faith, they will have personal liability to third parties.

JURISDICTION AND VENUE

25. This Court has original jurisdiction over the plaintiff's federal claims pursuant to 28 U.S.C. §§ 451, 1331, 1337, 1343. This action is authorized and instituted pursuant to the Lanham Act §43 (a), 15 U.S.C. § 1125(a) and the Sherman Act, 15 U.S.C. § 15

26. Venue is proper in the United States District Court for the Eastern District of Pennsylvania. A substantial part of the events giving rise to this claim occurred in the Eastern District of Pennsylvania.

FACTUAL ALLEGATIONS

27. While a post-doctoral fellow in the Viral Oncology program of the University of Miami Sylvester Comprehensive Cancer Center, Dr Andela was the primary investigator of research into the role of Epstein Barr Virus MicroRNAs in the pathogenesis and progression of Burkitt's lymphomas (the most common pediatric cancer in equatorial Africa that is associated with Epstein Barr Virus infection). Of note, a post-doctoral fellow ("post-doc") – as defined by the National Post-Doctoral Association – "is an individual holding a doctoral degree who is engaged in a temporary period of mentored research and/or scholarly training for the purpose of acquiring the professional skills needed to pursue a career path of his or her choosing […]. Post-docs are essential to the scholarly mission of the mentor and host institution, and thus are expected to have the freedom to publish the results of their scholarship."

28. Dr Andela's research into the role of Epstein Barr Virus (EBV) MicroRNAs in the pathogenesis and progression of Burkitt's lymphomas culminated in his identification of a novel immune evasion strategy employed by the EBV which involves a specific EBV microRNA (BHRF1-3 miRNA) targeting and suppressing the expression critical genes involved in cancer immune surveillance (cancer

immunity). Dr Andela further demonstrated that this novel EBV immune evasion strategy was amenable to therapeutic intervention.

29. A frivolous and superfluous aspect of the investigation which Dr Andela's "collaborators" at the University of Miami and the University of North Carolina at Chapel Hill forcibly pursued consisted in assessing the expression profile of EBV microRNAs in clinical cancer specimens. Dr Andela and the head of the viral oncology program at the University of Miami had made contact with senior investigators in Cameroon (Africa) and committed to funding and collaborating on a research program whose initial purpose was to obtain upwards of 50 fresh frozen clinical specimens of Burkitts Lymphoma for molecular analysis in the U.S. The commitments in Africa were wantonly dishonored and foreclosed. Thence, a heterogeneous set of 10 clinical specimens obtained from Brazil were foisted upon Dr Andela's research, irrespective of the fact that a sample size of 10 specimens – what's more a heterogeneous set of specimens - is not enough to establish any meaningful and statistically relevant gene expression signature. Thus a frivolous and superfluous dataset on EBV microRNA expression patterns in clinical tumor specimens was foisted upon Dr Andela's research manuscript for no other reason than to serve the predatory and monopolistic motives of his "collaborators" who sought the opportunity to misappropriate authorship credits on the research manuscript and diminish or exclude Dr Andela's hard-earned gains.

30. Dr Andela's research manuscript entitled "Targeted Suppression of CXCL11/I-TAC by EBV-encoded BHRF1-3 microRNA in EBV related B-Cell Lymphomas" was submitted for consideration to the highly regarded journal of the American Hematological Society *BLOOD* on the 1st of June 2006, and the authorship byline of the manuscript reads as follows:

> **Valentine B. Andela**: designed research, performed research, collected data, analyzed data, and wrote the paper; **Andrea Chaput**: performed research, collected data; **Iguarcyra Araujo**: performed path analyses; **Jose Barretto, Eny Carvalho:** contributed primary tumors, **Estella Luz** collected and processed tumors and performed research; **Juan Carlos Ramos, Celia Pedoros, Ngoc L. Toomey; Dirk Dittmer**: designed research, analyzed data and wrote the paper; **William J. Harrington**: designed research, analyzed data and wrote the paper.

31. Authorship credit on the manuscript is fallacious and does not accord with established guidelines which state that:

> A "responsible author" is one who receives or is included in a "byline" on a published report just in case s/he has made nontrivial intellectual contributions to the work described by the report. Despite that many decisions about publication and authorship require judgment calls, this position is accepted across the sciences and the humanities.
> The growth of knowledge and its applications require accurate, fair and appropriate credit. It is inappropriate to be listed as an author as a result of financial support, administrative leadership or technical assistance (such as mere data collection). One should not be listed as an author as a favor, as a courtesy or as an expression of gratitude.
> The International Committee of Medical Journal Editors – widely accepted as authoritative for biomedical scientists – says, "An 'author' is generally considered to be someone who has made substantive intellectual contributions to a published study…" The committee offers these criteria: Authorship credit should be based on **1**) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; **2**) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.
> Note that the guideline calls for meeting *all* three criteria.

32. Expert referees of the journal *Blood* reviewed Dr Andela's manuscript and their assessment was overwhelmingly positive EXCPEPT for the frivolous dataset on the clinical tumor specimens. The reviewers requested specific revisions in this area and the editor rejected the manuscript for publication.

33. While the required revisions essentially revolved around verifying the dataset on the clinical tumor specimens by a more quantitative and statistically robust methodology (which collaborators at the University of North Carolina at Chapel Hill had been contracted to do), Dr Andela's collaborators decidedly and deliberately compounded confounders upon his research. The following email was sent to Dr Andela:

> From: Harrington, William
> Sent: Sat 7/29/2006 11:34 AM
> To: Andela, Valentine
> Subject:
> This is what I think we should do. You are going away for 3weeks?? We should not wait around. Lets get the perforin data, the gel we cut out, the peterson cxcl-11 and the better of the dicer exps and **submit a brief definitive report to cancer research**. It will be reviewed why [sic] you are out so we wont waste time. **I will send it to a friend who is an editor and worst case scenario you are no worse off when you return.** During your absence I will have Lan do some more experiments to bolster this or, if necessary a resubmission to Blood. This is what I want to do. Barber says that **cancer research, especially one of those brief articles are much more highly considered than Blood**

In actuality *Blood* has a higher impact factor than *Cancer Research* and the only reasonable course of action was to remove the frivolous data on the clinical tumor specimens or address the *Blood* reviewer's critiques and resubmit to the manuscript for publication.

34. On the 11th of April 2007, Dr Andela's now former collaborators mutilated his original manuscript and resubmitted it to *Blood* under the title "Profiling of Epstein Barr virus (EBV) microRNAs in primary lymphomas uncovers CXCL11/I-TAC as a target for ebv-mir-BHRF1-3" (to wrongfully suggest that it is by examining the clinical tumor specimens that evidence of a novel immune evasion mechanism in Epstein Barr Virus related cancers had been uncovered) without so much as Dr Andela's approval and consent.

35. A quantitative dataset on the clinical tumor specimens which the reviewers had requested and which "collaborators" at the University of North Carolina at Chapel were contracted to provide was still not provided.

36. The narrative in the manuscript had been altered significantly and was very poorly articulated. A number of datasets had been mutilated. The authorship byline on the fraudulent manuscript had been changed to read:

> **Valentine B. Andela**: designed and performed the research; **Andrea O'Hara**: performed array studies; **Iguarcyra Araujo**: performed pathological analysis; **Jose Barretto and Eny Carvalho**: contributed

specimens; **Estrela.Luz and Celia Pederosa**: collected and processed specimens. **Ngoc.L.Toomey**. performed experiments. **Juan Carlos.Ramos**: contributed specimens and performed experiments; **Carlos.Brites**: performed experiments; **Dirk Dittmer**: performed real time PCR microarray; **William J. Harrington**: analyzed the data and co-authored the paper.

37. The manuscript was negatively reviewed by referees of *Blood* and rejected for publication by the editor of *Blood* on the 4th of May 2007.

38. Upon learning about this unlawful, unethical and defamatory act, Dr Andela filed a grievance with the editor of *Blood* stating that he had not authored and consented to the submission of the falsified manuscript.

39. On the 31st of August 2007, Dr Andela's original manuscript on Epstein Barr Virus MicroRNAs was plagiarized, falsified and submitted for publication to the journal *Cancer Research*.

40. With the complicity of the editors of *Cancer Research*, the manuscript was accepted for publication on the 23rd of December 2007. Upon acceptance, the "authors" authors signed a copyright transfer agreement with the publisher (the American Association for Cancer Research), an excerpt of which reads:

> PLEASE NOTE THAT **ALL** AUTHORS ON THE MANUSCRIPT MUST COMPLETE AND RETURN A COPYRIGHT TRANSFER FORM.
>
> Frank J. Rauscher, III
> Editor-in-Chief
>
> ☐
>
> In consideration of the fact that AACR, Inc., undertakes to publish my article:
> **Title** (Required):
> _____
> _____
> **Manuscript Number** (Required): **CAN-**_____ in a forthcoming issue of *Cancer Research*:
> 1. I affirm that the material in the above article has not been published previously and that I (and my coauthors) own and have not transferred elsewhere any rights to the article.
> 2. I affirm that I have obtained written permission to use any previously copyrighted material included in the article and that such documentation will be forwarded to the AACR Publications Department for its files.
> 3. I hereby assign and transfer to AACR, Inc., all exclusive rights of copyright ownership to the article, including without limitation all rights of reproduction, derivation, distribution, sale, and display of the work, in whole or in part, in any and all forms of media now or

> hereafter known, as protected by the laws of the United States and foreign countries. These exclusive rights will become the property of the AACR, Inc., from the date of acceptance of the article for publication in the journal *Cancer Research*. I understand that AACR, Inc., as copyright owner, has sole authority to grant permission to reproduce the article.

41. Dr Andela's plagiarized and falsified manuscript was subsequently published in March of 2008: EBV microRNAs in primary lymphomas and targeting of CXCL-11 by ebv-mir-BHRF1-3. Xia T, O'Hara A, Araujo I, Barreto J, Carvalho E, Sapucaia JB, Ramos JC, Luz E, Pedroso C, Manrique M, Toomey NL, Brites C, Dittmer DP, Harrington WJ Jr. *Cancer Research*. 2008 March 1;68(5):1436-42.

42. Plagiarism and falsification is theft of intellectual property and is not unlike theft from a commercial business. Irreparable harm has been done once a plagiarized and falsified research article has been published. Even publishing a retraction notice only signals the harm and does not cure it: retracted manuscripts remains cited in the literature. Plagiarism and falsification also qualifies as false advertising or promotion.

43. Driven by his moral right – i.e. an authors' connection to his work and the right and duty to protect the integrity of such work - over his research that had been plagiarized, falsified and falsely advertised, it was a categorical imperative and a duty for Dr Andela to engage in corrective advertising and to write and publish a "Letter to the Editor" in response to said article. The official editorial policy of *Cancer Research,* in regards to 'Letters to the Editor' states that:

> in the spirit of open scientific dialogue, the Editors invite the submission of correspondence that presents considered opinions in response to articles published in the journal. Letters to the Editor will be peer reviewed and, if found to meet the requisite publication criteria (scholarly commentary on a subject of importance and interest to the broad readership), the Letter may be sent to the author(s) of the originally published article and possibly to other interested parties for a response to be published in the same issue of the journal as the Letter. Please note that the journal will not consider Letters

to the Editor regarding Cancer Research articles that were published more than three months prior.

44. In April 2008, Dr Andela wrote a 'Letter to the Editor' that was a technical and scholarly critique of his work that had been plagiarized, falsified and published on the 1st of March 2008, issue 68, Volume 5, pages 1436-42 of *Cancer Research* under the title "EBV microRNAs in primary lymphomas and targeting of CXCL-11 by ebvmir-BHRF1-3".

45. On the 20th of May 2008, a Reviewer, an Associate Editor and the Editor-in-Chief of *Cancer Research* responded to Dr Andela's 'Letter to the Editor'

46. The Reviewer's comments were - per se – fraudulent, irrational, unscientific, dishonest, underhanded and unbecoming of the spirit of open scientific dialog and the deontology of the scientific research enterprise

47. The Associate Editor then disparaged Dr Andela and callously stated that:

> "An expert reviewer and the editors have evaluated this commentary. We do not feel that the analysis of the original paper and the objections to the interpretation of the data presented by the author of this commentary are compelling. <u>This commentary also lacks an in-depth understanding of the complexity of the system being evaluated</u>."

48. The Editor-in-Chief endorsed the Reviewer's "comments" and the Associate Editor's "recommendations" and rejected Dr Andela's 'Letter to the Editor' stating that:

> "In addition to the reviewer's comments, such factors as the Associate Editor's recommendation and the priority scores assigned to the work are taken into consideration. Only those manuscripts that meet stringent requirement of high scientific quality and significance, originality, and priority can be accepted"

49. On the 4th of June 2008, Dr Andela provided *Cancer Research* with the originating research manuscript entitled "Targeted Suppression of CXCL-11/I-TAC by EBV-Encoded BHRF1-3 microRNA in EBV-Related B-Cell Lymphomas" of which he is

the primary author and which had been submitted for consideration and had been for the most part favorably reviewed by the flagship journal the American Hematological Society, *Blood,* prior to being plagiarized, falsified and published with the complicity of editors of *Cancer Research* on the 1st of March 2008, in Issue 68, Volume 5, pages 1436-42, of *Cancer Research* under the title "EBV microRNAs in primary lymphomas and targeting of CXCL-11 by ebvmir-BHRF1-3".

50. Dr Andela made it amply clear in his correspondence to *Cancer Research* that the immediate remedy to this blot on the public research record and the violation of his moral and legal rights was the publication of his 'Letter to the Editor' and that the - per se – fraudulent, irrational, unscientific, dishonest, underhanded and unethical "peer review" and rejection of the 'Letter to the Editor' was an act of coercion, fraud and an unlawful conspiracy in restraint of trade and a violation of his moral and legal rights.

51. An e-mail response to Dr Andela dated June 16th 2008 from the Senior Associate Editor, Judy N. Quong, Ph.D, and upon which the Assistant Director, Editorial Systems & Journal Manager, Kelly A. Hadsell, and the Editor-in-Chief, Frank J. Rauscher III, Ph.D., were copied, reads thus in pertinent part:

> Thank you for your recent letter concerning the recently published article by Xia et al (Cancer Research, 2008 68: 1436-1442). While we have taken your concerns into consideration, after having reviewed all of the information we do not believe that the paper warrants retraction. Specifically, it appears that additional experiments were conducted subsequent to your departure from the laboratory and we cannot assess the events that led to the final version of the manuscript.

52. This email correspondence is further evidence of the defendants' conspiracy and a gross dereliction of the duties of ordinary care, good faith, candor, fair dealing and obedience to the public interest and to the deontology that underwrites the scientific research enterprise. As unequivocally expressed by a prominent ethicist and leading authority on scientific misconduct:

> "a moral climate that rejects stealing, defines it as a reprehensible act, and condemns the thief, instead of a climate that ignores plagiarism or fabrication or that excuses it according to the offender's status, will benefit everyone"

53. On the 11th of November 2008, an attorney acting on Dr Andela's behalf sent a letter to the defendant requesting immediate retraction of the plagiarized and falsified research article and providing marked up copies of Dr Andela's original manuscript that was submitted to *Blood* on the 1st of June, 2006; the mutilated version of Dr Andela's research manuscript that was submitted to *Blood* on the 11th of April, 2007 without Dr Andela's approval and consent and finally; the research article that Dr Andela's former collaborators published in *Cancer Research* on the 1st of March, 2008 (**for ease of reference, all sections that had been plagiarized and falsified were highlighted**)

54. On the 12th of December 2008, counsel for the Editor-in-Chief of *Cancer Research* took the position that those who submitted the Research Article in question were primarily responsible for investigating and correcting acts of misconduct.

55. Dr Andela retorted that the defendant had clearly conspired in the unlawful conduct and was independently responsible by failing to carry out its duty of ordinary care, good faith, candor, fair dealing and obedience to the public interest and the deontology of the scientific research enterprise.

56. In support of this claim, Dr Andela forwarded a copy of his 'Letter to the Editor' that had been submitted in response to clearly plagiarized and falsified research article and the - per se – fraudulent, irrational, unscientific, dishonest, unethical and underhanded responses he got from *Cancer Research* to their counsel for comment.

57. Counsel for *Cancer Research* did not respond or comment.

CLAIMS FOR RELIEF

CLAIM ONE:
Gross Dereliction of Duty, Fraud and Conspiracy to Defraud

58. The allegations in paragraphs 1 – 57 above are incorporated as if set forth fully herein.

59. A "MicroRNA Meeting Report" published in a May 15th, 2007 issue of *Cancer Research* (MicroRNA: Potential for Cancer Detection, Diagnosis, and Prognosis. *Cancer Research* 2007; 67: (10):4553–5.) clearly articulated on the basic requirements for reporting microRNA gene expression signatures in clinical specimens of a given cancer type as follows:

> a well defined clinical question, a statistically valid experimental design, selection of highly characterized cases appropriate to the question and representative of the population, consideration of tumor heterogeneity, identification of normal controls, a robust platform and robust statistical and computational analysis of diagnostics and predictors with independent validation.

60. The plagiarized and falsified research article in question, *"EBV microRNAs in primary lymphomas and targeting of CXCL-11 by ebvmir-BHRF1-3" Cancer Research*, *Issue 68, Volume 5, pages 1436-42*, provides EBV microRNA expression data on clinical lymphoma specimens that DOES NOT, BY ANY STRETCH OF THE IMAGINATION, meet the basic requirement articulated above. What's more, said the data was clearly falsified. The publication of such fallacious falsities was driven by the need to advertise and/or promote a cartel

61. The defendant knowingly, willfully and wantonly engaged in false advertising and failed in carrying out its duty of ordinary care, good faith, candor, fair dealing and obedience to the public interest and the deontology of the scientific research enterprise.

CLAIM TWO:
Coercion, Fraud and Conspiracy to Defraud

62. The allegations in paragraphs 1 – 61 above are incorporated as if set forth fully herein.

63. Plagiarism and falsification is theft of intellectual property and is not unlike theft from a commercial business. The plagiarism and falsification of Dr Andela's research constitutes false advertising and demanded some form of corrective advertising in the form of a 'Letter to the Editor'

64. Dr Andela's 'Letter to the Editor' written in response to *"EBV microRNAs in primary lymphomas and targeting of CXCL-11 by ebvmir-BHRF1-3" Cancer Research*, *Issue 68, Volume 5, pages 1436-42*, more than met the "stringent requirements of high scientific quality and significance, originality, and priority". It was a scholarly commentary and a reasoned critique by the primary author of the originating research manuscript that had been plagiarized, falsified and published in *Cancer Research*.

65. The "peer review" and rejection of Dr Andela's 'Letter to the Editor'/ 'Corrective Advertising' was - per se - fraudulent, irrational, unscientific, dishonest, unethical and underhanded.

66. The defendant unlawfully restrained Dr Andela's competitiveness in the market.

67. The defendant perpetrated a fraud and failed in carrying out its duty of ordinary care, good faith, candor, fair dealing and obedience to the public interest

CLAIM THREE:
Intentional Infliction of Emotional Distress

68. The allegations in paragraphs 1 – 67 above are incorporated as if set forth fully herein.

69. The - per se - fraudulent, irrational, dishonest, unscientific, unethical and underhanded "peer review" of Dr Andela's 'Letter to the Editor'/'Corrective Advertising' written in response to *"EBV microRNAs in primary lymphomas and*

targeting of CXCL-11 by ebvmir-BHRF1-3" Cancer Research, *Issue 68, Volume 5, pages 1436-42* was an outrageous conduct pursued with actual malice and with reckless and callous disregard for Dr Andela's physical and emotional well being and constitutional rights.

70. As the primary investigator who put his heart and soul into working out the crux of the research article in question – i.e. the identification of a novel immune evasion mechanism in Epstein Barr Virus related Burkitts lymphomas (the most common childhood cancer in equatorial Africa) that is amenable to therapeutic intervention - Dr Andela's sense of purpose and moral right is profoundly violated and irreparably injured by the defendant's fraudulent and coercive actions.

71. Dr Andela has suffered irreparable injuries to his reputation and has lost work and future prospects for work and is consequently suffering emotional distress, depression and a contracted social life, and other related harms.

72. The defendant acted both oppressively and maliciously with the intent to cause injury to Dr Andela and with conscious disregard for Dr Andela's moral rights. As such, Dr Andela is entitled to punitive damages, in addition to compensatory damages, as permitted by law.

CLAIM FOUR:
Willful Violation of the Lanham Act § 43(a), 15 U.S.C. § 1125 (a)

73. The allegations in paragraphs 1 – 72 above are incorporated as if set forth fully herein.

74. The Lanham Act § 43(a), 15 U.S.C. § 1125 (a), outlaws any form of false advertising including advertisements based on flawed and insignificant research or representations found to be unsupported by accepted authority or research or which are contradicted by prevailing authority or research. Furthermore, the Lanham Act outlaws commercial defamation/disparagement of a competitors' product. The Lanham Act states that:

> **(1)** Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which—
>
> > **(A)** is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or **(B)** in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

75. There are false designations of origin, false and misleading descriptions of fact, and false and misleading representations of fact in the research article entitled *"EBV microRNAs in primary lymphomas and targeting of CXCL-11 by ebvmir-BHRF1-3" Cancer Research*, *Issue 68, Volume 5, pages 1436-42*, that was "peer reviewed", owned (upon signing of copyright transfer agreement), published and disseminated by the defendant.

76. The false designations of origin, false and misleading descriptions of fact, and false and misleading representations of fact in the research were used in commercial advertising or in the promotion of commercial interests of a cartel.

77. The defendant's false designations of origin, false and misleading descriptions of fact and false and misleading representations of fact have caused harm to Dr Andela (Cancer-Africa™) and also to the medical market.

78. Dr Andela (Cancer-Africa™) has suffered economic harm - through the forceful and fraudulent interference of his prospective economic advantage - proximately caused by the defendants' conspiracy in a predatory, exclusionary and anticompetitive enterprise.

79. The defendant intentionally, forcefully and fraudulently interfered with Dr Andela's efforts at correcting the research record by disparaging, blurring and tarnishing Dr Andela's trade dress (Cancer-Africa™).

80. The market is distorted by such false designations of origin, false and misleading descriptions of fact, and false and misleading representations of fact in as much as research accomplishments and priorities are distorted, medical discovery is confounded and innovation is foreclosed.

CLAIM SIX:
Violation of the Sherman Antitrust Act, 15 U.S.C. §§ 1,2

81. The allegations in paragraphs 1 – 80 above are incorporated as if set forth fully herein.

82. The Sherman Antitrust Act governs and promotes competition and consumer welfare and the wording of the Sherman Antitrust Act reflects common law. The first two sections read as follows:

> **Section 1**: Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.
>
> **Section 2**: Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

83. The defendant's "nonprofit" corporate veil belies the fact that a significant segment of its membership, board of trustees and activities are profit-driven and highly prone to cartelization. The defendant failed in carrying out its duty of ordinary care, good faith, candor, fair dealing and obedience to the public interest and is clearly not exempt of antitrust laws.

84. As "the world's oldest and largest professional organization dedicated to advancing cancer research" by working to "marshal the full spectrum of expertise from the cancer community to accelerate progress in the prevention, diagnosis and treatment of cancer through high-quality scientific and educational programs" such as publishing *Cancer Research*, "the most frequently cited cancer journal in the world.", the defendant possesses power in the relevant market including the power to limit cartelization or exclusionary monopolies and to redress exclusionary and predatory acts that result in harm to competition, distort markets and increase barriers to entry. The defendant's non-profit mandate and duty of ordinary care, good faith, candor, fair dealing and obedience to the public interest and the deontology of the scientific research enterprise, is exercised through the management of knowledge flows and funding streams by such mechanisms as the scientific peer review process.

85. In a conduct-specific test, the defendant fails to meet its non-profit mandate and duties of ordinary care, good faith, candor, fair dealing and obedience to the public interest and consumer welfare as reflected in the - per se – fraudulent, irrational, dishonest, and underhanded peer review and rejection for publication of Dr Andela's 'Letter to the Editor' written in response to an evidently plagiarized and falsified research article (which in itself was a predatory, exclusionary and anticompetitive act).

86. There is no legitimate business justification for the defendant's use of coercion and fraud in restraining Dr Andela's market activity nor is there any legitimate

justification for engaging in exclusionary, predatory, monopolistic and anticompetitive conducts. The evidence clearly indicates a barrage and barrier to Dr Andela and his business instrument (Cancer-Africa™).

87. Dr Andela (Cancer-Africa™) has suffered and will continue to suffer injury to his business and property.

88. The defendant's conduct has caused and will continue to cause injury to the relevant market in the form of distortions, slower innovation, higher prices and limited consumer choice.

89. As a global public non-profit corporation, the defendant's mandate is to prevent a "tragedy of the (anti)commons" in the marketplace by exercising its moral authority and prevailing upon a "(anti)commons dilemma" whereby multiple individuals acting independently in their own self-interest can ultimately destroy a shared limited resource (commons) or artificially limit a resource by exercising rival excludable rights (anticommons) even though it is clear that it is not in anyone's long term interest for this to happen.

90. The relevant geographic marketplace is the world and the marketplace for cancer research and services is fraught with anticompetitive practices that harm competition, distort markets, increase barriers to entry, restrict output, increase prices and ultimately reduces consumer welfare and access to life saving therapies.

91. There is a compelling and binding precedent and a rational expectation which Dr Andela (Cancer-Africa™) stands up to reassert and capitalize upon: much of the proof of principle and existing algorithms in clinical cancer chemotherapy were gleaned and established in the course of international clinical trials on the African Burkitt's lymphoma that were conducted in Africa in the 1960's i.e. at the cusp of Africa's independence and with the active participation and intrinsic contribution of the locals. These successes were celebrated in the 1972 Albert Lasker Award

(generally considered the American equivalent of the Nobel Prize in Medicine) for medical research on the chemical treatment of cancer and were critical to the enactment of the National Cancer Act in 1971 and its promulgation as "The War Against Cancer" by President Richard Nixon.

92. The critical contribution of Africa, while recognized in the 1972 Albert Lasker Award, is prominently absent from subsequent narratives such as a recent review article entitled "A History of Cancer Chemotherapy" which is published as part of the AACR Centennial Series in *Cancer Research*, November 1, 2008; Issue # 68: Volume 21, pages 8643-8653. The systemic and systematic exclusion of Africa from this "historical" narrative plays into a "tragedy of the anticommons" and only goes to harm competition, distort markets, increase barriers to entry, restrict output, increase prices and ultimately reduce consumer purchasing power and access to life saving therapies across the board.

93. Cancer remains a leading cause of morbidity and mortality and is associated with incalculable pain, suffering and catastrophic health spending. Every projection indicates a rising cancer burden coupled to spiraling cost increases in cancer care. The Pharmaceutical Research Manufacturers of America (PhRMA) estimated that of the 400 cancer medicines that were being tested in clinical trials in 2005, a significant fraction did not prove useful and the many that did faced delays in getting approved because clinical participants were low (<3% of U.S. patients participate in clinical trials) because of cost constraints ((N.B. 70-90% of the cost of conducting clinical trials in the U.S. are administrative costs). As such, the cost of research and development increases and this cost increase is passed on to the end consumer who is in turn constrained by the cost of access to life saving therapies and the end result is a vicious cycle of spiraling costs.

94. New knowledge would again be gleaned from an international research effort in Africa especially given that its mosaic population genetics is essential to laying

bare all of the complexities and contrasts in cancer biology and accelerating the development of the new generation of targeted cancer therapies. Moreover, there is a tremendous wealth of cancer patients available for enrollment in clinical trials at a fraction of cost in Africa. However, accessing and effectively engaging this resource pool starts with a "fundamental extension in morality."- to paraphrase the subtitle of the landmark essay on "The Tragedy of the Commons" - published in the most highly regarded scientific journal of the American Association for the Advancement of Science, *Science*, in 1968 – which is central to all debates in economics, law and science that revolve around the privatization of the commons.

95. That the defendant – in spite of its status and mandate as a global public non-profit corporation - would knowingly and willfully participate predatory, exclusionary and anticompetitive activities constitutes a major and profound lapse in morality and corporate responsibility.

PRAYER FOR RELIEF

96. WHEREFORE PLAINTIFF PRAYS THIS COURT:

A) Comply with the prevailing policy of the U.S. Department of Justice in terms of vigorous antitrust enforcement;

B) Pierce the corporate veil and recognize that the defendant(s) collectively and individually violated the Lanham Act § 43(a), 15 U.S.C. § 1125 (a);

C) Pierce the corporate veil and recognize that the defendant(s) collectively and individually violated the Sherman Antitrust Act, 15 U.S.C. §§ 1,2;

D) Award treble general and compensatory damages, in an amount to be proven at trial, pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15(a) and the Lanham Act, 15 U.S.C. § 1117, or award statutory damages pursuant to the Sherman Antitrust Act, 15 U.S.C. §§ 1, 2, as compensation for past and

future economic losses, loss of future career prospects and other injuries proximately caused and enhanced by defendants wrongful conduct including irreparable injuries to reputation and emotional suffering;

E) Award punitive damages, to punish the defendants for outrageous conduct pursued with actual malice and with a reckless and callous disregard of the plaintiff's physical and emotional well being and constitutional rights; to discourage defendants from engaging in similar conduct in the future; and to deter others similarly situated from engaging in similar conduct;

F) Grant a mandatory injunction amounting to correcting the public research record and prohibiting the defendants from engaging in any further conduct unlawful under the Lanham Act and the Sherman Antitrust Act;

G) Award of attorneys' fees and costs, pursuant to 42 U.S.C. 1988;

H) Grant a trial by jury; and such other or further relief as the Court may deem just and proper.

Respectfully submitted,

This 18th Day of June, 2009

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ENCLOSURES:
Exhibit I – Curriculum Vita _ Valentine Andela
Exhibit IIA – Letter to the Editor and Editorial Response
Exhibit IIB – June 4th 2008 Correspondence to the Editor-in-Chief of Cancer Research
Exhibit IIC – June 18th 2008 Email Correspondence from the AACR
Exhibit IID – November 11th 2008 Correspondence (with **marked up manuscript**)
Exhibit III – January 5th 2009 Correspondence to Counsel for the AACR
Exhibit IV – Pertinent "MicroRNA Meeting Report" Published 15th of May 2007
Exhibit V – Official Pronouncements, Recipients and Jury of the 1972 Lasker Award
Exhibit VI – "History of Cancer Chemotherapy", Published 1st of November. 2009
Exhibit VII – U.S. Department of Justice: Prevailing Antitrust Enforcement Policy
CC (w/o enclosures):
American Association for Cancer Research
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